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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,905	11/10/2000	Kalyanaraman Ramnarayan	24737-1906C	3606
24961	7590	02/19/2004		
HELLER EHRMAN WHITE & MCAULIFFE LLP 4350 LA JOLLA VILLAGE DRIVE 7TH FLOOR SAN DIEGO, CA 92122-1246				
			EXAMINER BRUSCA, JOHN S	
			ART UNIT 1631	PAPER NUMBER

DATE MAILED: 02/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/709,905	Applicant(s) RAMNARAYAN ET AL.	
	Examiner John S. Brusca	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25, 45-50, 66, 67, 87-90 and 95-127 is/are pending in the application.
- 4a) Of the above claim(s) 102, 103, 105, 106, 108 and 109 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/03/03</u> | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-25,45-50,66,67,87-90,95-101,104,107 and 110-127.

DETAILED ACTION

Election/Restrictions

1. In response to the notice of a nonresponsive amendment mailed 02 July 2003 the applicants filed a petition under 37 CFR 1.181 on 14 August 2003 requesting entry of the amendment originally filed 03 June 2003. Due to delay by the Office, a decision on the petition was not mailed until 26 November 2003. The petition decision states that because the amended claims continue to read on ab initio methods of structure determination, the amended generic claims are not that of a different invention, but are merely broader than that of the originally filed claims and are therefore a responsive amendment that should be entered. The non-responsive notice is vacated and the amendment filed 03 June 2003 has been entered into the specification. The petition decision goes on to state that if the originally filed claims are determined to be limited to methods requiring an ab initio method of structure determination, the application may be considered to have elected ab initio methods by original presentation. If such is the case, Office policy is to withdraw claims drawn to species other than ab initio methods.
2. In the petition filed 14 August 2003, the applicants argue that the originally filed claims were not limited to methods of structure determination requiring ab initio methods because the claims do not recite the term “ab initio” and the specification describes many methods of structure determination.
3. Upon consideration of the applicant’s arguments, it is maintained that the original claims were limited to ab initio methods because of the recitation in all originally filed claims of the phrase “generating 3-dimensional (3-D) protein structural variant models from the sequences” because such a step excludes data from sources such as experimental methods or database

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correlations, and requires that the structure is determined ab initio from the sequence data alone.

The applicant's amendment amends the phrase to recite "determining 3-dimensional (3-D) protein structural variant models for the target proteins that are the product of a gene exhibiting genetic polymorphisms" which is broader because it is not limited to any single method of determining the structure.

4. Newly submitted claims 101-109 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 101, 104, and 107 are Markush-type claims that read on methods of structure determination other than ab initio methods, namely experimental methods, searching databases, homology modeling, de novo protein folding, computational protein structure prediction, and combinations thereof, and will be examined only as they read on ab initio methods as discussed in MPEP 803.02. Claims 102, 103, 105, 106, 108, and 109 are withdrawn as they are drawn to methods of structure determination other than ab initio methods, namely either X-ray crystallography and NMR spectroscopy, or a combination of homology modeling and ab initio methods.

5. Claims 1-25, 45-50, 66, 67, 87-90, 95-100, 110-127 are generic with respect to the method of structure determination.

6. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 102, 103, 105, 106, 108, and 109 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. The originally filed claims were not anticipated or obvious over the prior art because of the lack of enablement of all claims made of record in the Office action mailed 03 December 2002. In view of the entry of the generic claims of the amendment filed 03 June 2003 it apparent that a search of target proteins will be required to consider prior art anticipation or obviousness of the instant claims. As such, a new restriction requirement for a species of target protein is made below.

8. This application contains claims directed to the following patentably distinct species of the claimed invention:

The species of target protein are:

1) HIV protease (claims 6-10, with claims 9 and 10 being subspecies of claims 6-8 drawn to SEQ ID NOS: 3-74 and 77-117)

2) enzymes (claims 45-47, 49, 50, 115-117, 119, and 120) with claims 46 and 116 being subspecies of claims 45 and 115 drawn to proteases, or polymerases, and claims 47 and 117 being drawn to a single subspecies of polymerases consisting of reverse transcriptases, claims 49 and 119 being drawn to a subspecies of infectious agent enzymes, and claims 50 and 120 being drawn to a single subspecies of HIV agents.

3) infectious agent proteins (claims 48 and 118)

4)human proteins (claim 125)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. For the HIV protease species, a single SEQ ID NO subspecies must be elected as detailed below. For the enzyme species, a single subspecies of protease, polymerase, or infectious agent enzyme must be elected.

Currently, claims 1-5, 11-25, 66, 67, 87-90, 95-101, 104, 107, 111-114, 121-124, 126, and 127 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Sequence Election Requirement Applicable to the HIV protease species:

The HIV protease species detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied. The Applicants must elect a single SEQ ID Number.

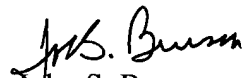
Examination will be restricted to only the elected sequence and additional sequences are not subject to rejoinder.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is (517) 272-0714. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (517) 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


John S. Brusca
Primary Examiner
Art Unit 1631

jsb